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Canadian Adverse Reaction Newsletter

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Scope

This quarterly publication alerts health professionals to potential signals detected through the review of case reports submitted to Health Canada. It is a useful mechanism to disseminate information on suspected adverse reactions to health products occurring in humans before comprehensive risk–benefit evaluations and regulatory decisions are undertaken. The continuous evaluation of health product safety profiles depends on the quality of your reports.

Reporting Adverse Reactions

Contact Health Canada or a Canada Vigilance Regional Office free of charge

Phone: 866 234-2345
Fax: 866 678-6789

Online form available at:

www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/index_e.html

Intravenous immune globulin: myocardial infarction and cerebrovascular and thrombotic adverse reactions

In Canada the use of intravenous immune globulin (IVIG) is reported to have increased by approximately 115% over the past 7–8 years, making Canada one of the highest per capita users of IVIG in the world.[1] In this context of increasing use, it is important that health professionals recognize some of the serious adverse reactions (ARs) suspected of being associated with the use of these products.

IVIG consists mostly of concentrated IgG manufactured from large pools of human plasma. Health Canada has authorized the use of a number of commercial brands for such indications as replacement therapy for primary or secondary immunodeficiency syndromes and treatment of idiopathic thrombocytopenic purpura. In addition, IVIG is often used off-label either as a passive immunizing agent or as an immunomodulator for the treatment of a growing number of conditions.[2]

From October 1997 to July 2007, Health Canada received 10 reports of stroke (reported as stroke, mini stroke, cerebral infarction or cerebrovascular accident), 6 reports of thrombosis (reported as thrombosis, thrombophlebitis or deep venous thrombosis), 4 reports of myocardial infarction (MI), 2 reports of pulmonary embolus and 1 report of transient ischemic attack (TIA) suspected of being associated with IVIG. Of the 21 patients involved, 2 had more than one AR. The median age was 61 (range 28–88, age not provided in 1 report).

The suspected products were reported as Gammagard S/D (stroke, MI, pulmonary embolism, thrombosis), Gamunex/IGIVnex (thrombosis, stroke, TIA) and Gamimune N (stroke, MI); the brand of IVIG was not specified in 3 reports (stroke, MI, thrombosis). The product monographs of all IVIG products marketed in Canada include information on the risk of thrombotic ARs.

Two patients received IVIG for common variable immune deficiency, and 17 were prescribed it off-label for polyneuropathy (4 reports), myositis (3), myasthenia gravis (2), dermatologic conditions (3) and other conditions (5). The indication for IVIG was not documented in 2 reports.

The number of days between the infusion of IVIG and the ARs varied depending on the type of reaction. Nine reported strokes occurred within a day after the IVIG administration, with most occurring during the infusion; the tenth stroke occurred 3 days after the last dose. Three MIs occurred during the infusion, and the fourth occurred 9 days later. The ARs occurred within 1 day of IVIG administration for TIA, within 11 days for pulmonary embolism and within 2 weeks for thrombosis.

Information on dose and infusion rate was often lacking or incomplete in the reports. Risk factors for the

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reported ARs were documented in all the reports of MI, pulmonary embolism and TIA, in 8 of the 10 reports of stroke and in 4 of the 6 reports of thrombosis. Strokes resulted in the most serious outcomes (1 death, 4 cases of persistent sequelae).

Serum viscosity has been shown to increase following IVIG administration.[3] Although several possible mechanisms have been proposed,[4] some authors have postulated that the change in serum viscosity during IVIG administration together with mild dehydration and other risk factors (e.g., age, atherosclerosis) contribute to the development of a "threshold" facilitating the production of thrombotic ARs.[4] Five reports noted the concomitant use of diuretics, which may have contributed to a rise in serum viscosity.

Health care professionals are encouraged to report ARs suspected of being associated with the use of IVIG and to include any available information that could help characterize potential risk factors.

Carole Légaré, MD, Health Canada

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1. Hume HA, Andersson DR. Guidelines for the use of intravenous immune globulin for hematologic and neurologic conditions. *Transfus Med Rev* 2007;21:51-2.
2. Constantine MM, Thomas W, Whitman L, et al. Intravenous immunoglobulin utilization in the Canadian Atlantic provinces: a report of the Atlantic Collaborative Intravenous Immune Globulin Utilization Working Group. *Transfusion* 2007;47(11):2072-80.
3. Steinberger BA, Ford SM, Coleman TA. Intravenous immunoglobulin therapy results in post-infusional hyperproteinemia, increased serum viscosity and pseudohyponatremia. *Am J Hematol* 2003;73(2):97-100.
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Case presentation

Recent Canadian cases are selected based on their seriousness, frequency of occurrence or the fact that the reactions are unexpected. Case presentations are considered suspicions and are presented to stimulate reporting of similar suspected adverse reactions.

Etonogestrel–ethinyl estradiol vaginal ring (NuvaRing) and aortic thrombosis

A 21-year-old obese woman (body mass index 36.3 kg/m²) who smoked 10–20 cigarettes per day experienced an aortic thrombosis 15 months after she started using the etonogestrel–ethinyl estradiol slow-release vaginal ring (NuvaRing) for contraception. Following an aortic thrombectomy, an embolus was also removed from her left leg. Her contraceptive history included low-dose desogestrel–ethinyl estradiol pills (Marvelon) and medroxyprogesterone injection (Depo-Provera). The reporter indicated that the patient had an elevated fibrinogen level of 6.4 (normal 2–4) g/L but no known fibrinolytic system disorder. She had no known history of varicose veins, recent injection or infusion, long-distance travel, prolonged immobilization, surgery or trauma. Her personal and family history of venous thrombosis was also negative.

Canada Vigilance: a new name and database for the Canadian Adverse Drug Reaction Monitoring Program

Health Canada is pleased to announce Canada Vigilance as the new name for the Canadian Adverse Drug Reaction Monitoring Program. The Program is also implementing a new database that will provide an enhanced capacity for the postmarketing surveillance of adverse reactions (ARs). The Canada Vigilance database will contribute to the ongoing assessment and communication of health product safety information. Health Canada, through the Canada Vigilance Program, is responsible for the collection and assessment of AR reports that have been submitted by health professionals or consumers, either directly or through Market Authorization Holders. Since 1965, Health Canada has been gathering information on suspected ARs to health products (pharmaceuticals, biologics [e.g., fractionated blood products, and therapeutic and diagnostic vaccines], natural health products and radiopharmaceuticals).

The new name also applies to our regional offices. The 7 Canada Vigilance Regional Offices (located in Vancouver, Edmonton, Saskatoon, Winnipeg, Toronto, Montréal and Halifax), in addition to the National Office (in Ottawa), will continue to collect AR reports. For more information on the Canada Vigilance Program and its database, and on other initiatives from the Marketed Health Products Directorate, visit the MedEffect Canada website at www.healthcanada.gc.ca/medeffect.

Adverse reactions (ARs) to health products are considered to be suspicions, as a definite causal association often cannot be determined. Spontaneous reports of ARs cannot be used to estimate the incidence of ARs because ARs remain underreported and patient exposure is unknown.

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Transdermal norelgestromin–ethinyl estradiol (Evra): myocardial infarction and thromboembolic adverse reactions

Evra is a transdermal hormonal contraceptive system containing 6 mg of norelgestromin and 0.6 mg of ethinyl estradiol per patch. Since its introduction on the Canadian market in early 2004, 16 cases of thromboembolism and 1 of myocardial infarction suspected of being associated with the product have been reported to Health Canada (Table 1). Two of the 17 patients died.

Hormonal contraception is one of the known risk factors for venous thromboembolism (VTE). Others include prolonged immobility, major surgery, family history of VTE, increasing age, smoking and obesity (body mass index [BMI] ≥ 30 kg/m^2).[1-5] The risks may be cumulative if more than one risk factor is present.[1] An association between overweight (BMI $\geq 25 < 30$ kg/m^2) and thrombosis has also been observed among women using oral contraceptives.[6] The combined effect of obesity or overweight and oral contraceptive use was greater than the expected risks based on their individual effects.[6] The risk of VTE is also reported to be higher during the first 3 postpartum months than during pregnancy.[7] The product monograph states that women should be encouraged to use a nonhormonal form of contraception in the 3 months following delivery.[5]

Pascale Springuel, BPharm, RAC, Health Canada

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Table 1: Summary of reports submitted to Health Canada of myocardial infarction and thromboembolic disorders suspected of being associated with Evra, from date marketed in Canada to Aug. 27, 2007*

Case	Age, yr	Adverse reaction (AR)†	Time to onset‡	Outcome§	Risk factors and additional information
1	32–33	Myocardial infarction	"A few months"	Death	"Heavy patient"; smoker
2	35	Pulmonary embolism	3 months	Recovered without sequelae	Weight 57 kg; nonsmoker
3	NA	Pulmonary embolism	Unknown	Unknown	No information on risk factors available
4	37	Pulmonary embolism	7–8 days	Not recovered at time of reporting	Weight 87 kg; nonsmoker
5	23	Pulmonary embolism	3–4 months	Unknown	BMI 26.6 kg/m^2; stopped smoking 6 weeks before pulmonary embolism
6	25	Pulmonary embolism	1.5 years	Unknown	BMI 22.5 kg/m^2
7	16	Pulmonary embolism	1–2 months	Death	BMI 24 kg/m^2; Evra therapy initiated 9 weeks after cesarean section¶
8	NA	Deep venous thrombosis	Unknown	Unknown	No information on risk factors available
9	29	Deep venous thrombosis	14 months, but Evra use stopped 5–6 weeks before AR	Unknown	Weight 62 kg; quit smoking 1 year earlier
10	30	Deep venous thrombosis	Unknown	Unknown	No information on risk factors available
11	NA	Deep venous thrombosis	4 months	Unknown	No information on risk factors available
12	27	Arm thrombophlebitis	6 months	Not recovered at time of reporting	BMI 24.7 kg/m^2; nonsmoker
13	NA	Thrombosis/ embolism-blood clot	Unknown	Unknown	No information on risk factors available
14	28	Thrombophlebitis/ embolism-blood clot	2–3 years**	Unknown	No information on risk factors available
15	25	Thromboembolism	Unknown	Unknown	No information on risk factors available
16	15	Deep leg thrombophlebitis	5 weeks	Unknown	Smoker; family history of deep vein thrombosis
17	34	Deep leg thrombophlebitis	2–4 months	Unknown	Overweight (exact weight not provided); nonsmoker

Note: NA = not available, BMI = body mass index.

***These data cannot be used to determine the incidence of adverse reactions (ARs) because ARs are underreported and neither patient exposure nor the amount of time the drug was on the market has been taken into consideration.**

†Terms are listed according to the *World Health Organization Adverse Reaction Terminology* (WHOART).

‡Estimated from the beginning of the treatment.

§At the time of reporting, as indicated by the reporter.

¶Conflicting data: one source reported that therapy was initiated immediately after cesarean section.

**Conflicting data: report stated that therapy with Evra was initiated in 2002; however, Evra has been marketed in Canada only since January 2004.

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7. Heit JA, Kobbervig CE, James AH, et al. Trends in the incidence of venous thromboembolism during pregnancy or postpartum: a 30-year population-based study. *Ann Intern Med* 2005;143:697-706.

Summary of health professional and consumer advisories posted by Health Canada from Aug. 17 to Nov. 10, 2007

(advisories are available at www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index_e.html)

Date	Product	Subject
Nov 6 & 1	Rosiglitazone	New restrictions due to cardiac safety concerns — GlaxoSmithKline Inc.
Nov 5	Trasylol	Manufacturer temporarily suspends marketing in Canada
Nov & Oct 15	Sprint Fidelis Lead	Recall and patient management recommendations — Medtronic of Canada Ltd.
Oct 25	Foreign products	Foreign product alerts: Xie Gan Wan; Red Yeast Rice, Red Yeast Rice/Policosonal Complex and Cholestrix
Oct 18	Definity	Serious cardiopulmonary reactions — Bristol-Myers Squibb Canada
Oct 11	Cough and cold products	Recommendations for the appropriate use in children
Oct 5	Colleague pumps	Issue concerning the triple-channel infusion pumps — Baxter Corporation
Oct 5	Complete All-in-One	Update on recall
Oct 4 & 3	Prexige	Withdrawal of market authorization — Novartis Pharmaceuticals Canada Inc.
Oct 2	Calabash chalk	Health risk for pregnant and breastfeeding women
Oct 1 & Sept 28	Foreign products	Foreign product alerts: Gu Ci Dan and Xu Log Bou; Zhen Feng Da Brand Xi Tong Wan (lot no. 060908) and Wellring Brand Yin Qiao Jie Du (lot no. 51005); Asam Urat Flu Tulang, PJ Dewandaru; Khun-Phra
Sept 24	Vitamin D	Information update: vitamin D and health
Sept 21	Foreign products	Foreign product alerts: Top Gun for Men Herbal Extracts; Oyster Plus; Deguozhanjiang; Chongcaoliubian Jiaonang and Santi Scalper Penis Erection Capsule
Sept 19	Sodium Phosphates injection	Recall due to aluminum content — Pharmaceutical Partners of Canada
Sept 17 & 13	Foreign products	Foreign product alerts: Jacaranda, Queenmer Fat Loss, Li Da Dai Dai Hua Jiao Nang, J-minus and Jelimel Slimming Capsules; Junyu Jiaonanyihao; Satis 60 Hours Ever Lasting Formula; Qiangli Zhuanggutongbiling, Heng Tong Jiangtangning Jiaonang; Endopile Capsules; BuXie PaiDu XiaoDou Su; True Man and Energy Max
Sept 12	Precision Xtra	Information on blood glucose monitor — Abbott Diabetes Care
Sept 10	Viracept	Process-related impurity and guidance on its use — Pfizer Canada Inc.
Sept 10	Colloidal Silver Water	Unauthorized product that may pose health risk
Sept 4	Iressa	Failure to demonstrate non-inferiority in overall survival versus docetaxel — AstraZeneca Canada Inc.
Sept 5 & Aug 30	Ketek	Removal of sinusitis, bronchitis and tonsillitis/pharyngitis indications — Sanofi Aventis Canada Inc.
Aug 24	Toothpaste	Neem Active Toothpaste: additional health risks
Aug 17	Metaboslim capsules	Recall
Aug 17	Foreign products	Foreign product alert: Excite for women and Ultimates for men
July 23	IV Administration Sets	Safety alert notification — Cardinal Health
July 9	Thelin	Liver toxicity, risks to the fetus and important drug–drug interactions — Encysive Canada Inc.

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